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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,116	03/10/2006	Ramalingam Manikandan	RLL-278US	8409
7590 08/27/2007 Jayadeep R. Deshmukh Ranbaxy Inc. 600 College Road East, Suite 2100 Princeton, NJ 08901			EXAMINER HUANG, GIGI GEORGIANA	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 08/27/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/523,116

Applicant(s)

MANIKANDAN ET AL.

Examiner

GiGi Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7, 19, 21-24, 26, 28-31, 37, 38, 46 and 53 is/are pending in the application.
- 4a) Of the above claim(s) 28-31, 37, 38, 46 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 19, 21-24 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/5/2005.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. The inventions listed as Groups I – III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I, claims 1-7, 19, 21-24, and 26, drawn to methods of manufacturing water-dispersible tablet of cephalexin.

Group II, claims 28-31, 37-38, and 46, drawn to the composition of a water-dispersible form of cephalexin.

Group III, claim 53, drawn to methods of use of treating an infection with a water-dispersible tablet of cephalexin.

The technical feature linking Groups I – III is cephalexin in a water dispersible form.

Van Koutrik (WO99/18965) teaches a composition and methods of manufacture of a cephalosporin (cephalexin) antibiotic. The composition is an oral form and capable of reducing under wet conditions with high amounts of the active ingredient for adequate bioavailability profiles (Abstract, Page 5, lines 1-31, Page 6, lines 16-29).

Therefore, the technical feature linking the inventions of Groups I – III does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

Accordingly, Groups I – III are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

A telephone call was made to George Heibel who orally elected Group I on July 23, 2007 without traverse on the above restriction requirement is acknowledged.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Status of Application***

3. Applicant has elected Group I in response to restriction requirement for the examination.

4. Due to restriction, based on election of Group I, claims 28-31, 37-38, 46, and 53 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Claims 8-18, 20, 25, 27, 32-36, 39-45, 47-52 have been cancelled.

6. Claims 1-7, 19, 21-24, 26 are present for examination at this time.

***Information Disclosure Statement***

7. The information disclosure statement filed July 5, 2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because there is no translation for the abstract of the patent for FR 2 814 679. The reference has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

***Claim Rejections - 35 USC § 112***

8. Claims 1-7, 19, 21-24, 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a method of manufacture of a tablet of cephalexin wherein the process has no specific endpoint for the tablet that is being manufactured. It is unclear where the process ends and what the process is actually manufacturing. It does not adequately claim the subject matter for one of skill in the art to distinguish the metes and bounds of the art.

***Claim Rejections - 35 USC § 103***

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9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-7, 19, 21-24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olthoff et al. (EP 0281200) as applied to claims 1-7, 19, 21-24, and 26 above, and in view of Handbook of Pharmaceutical Excipients.

Olthoff et al. teaches a process of preparation of a pharmaceutical tablet for amphoteric beta-lactam antibiotics comprising two different disintegrants and other excipients. Examples 11-19 are presented for the production of a fast disintegrating tablet, less than one minute, comprising cefalexin monohydrate. A granulate was produced by wet granulation by comprising microcrystalline cellulose (a disintegrant and a suspending agent), cefalexin monohydrate (drug), and water (solution for binding).

The components were mixed, milled, dried, milled again and sieved. Wet granules were dried in a fluidized bed dryer. Particle size distribution for the granulate was less than 700um, the majority less than 500um, and a substantial portion of the particles were less than 150um. The granulate was mixed with the remaining part of the disintegrants, and other adjuvants, and then compressed into tablets. The adjuvants utilized in the examples included sweeteners (saccharin at about 1%), additional disintegrants (including croscarmellose sodium:Ac-Di-Sol, crospovidone:Kollidon CL, sodium starch glycolate:Primogel), flavors, suspending agents like colloidal silicon dioxide or microcellulose, and antiadherents such as and magnesium stearate/colloidal

silicon dioxide (Abstract, Page 4, lines 55-60, Page 5, lines 1-39, Page 7, Example 11-19, Page 8, Example 12-19).

Olthoff et al. does not expressly teach the use of colloidal silicon dioxide in the granulate or the coloring agent D&C Yellow Aluminum Lake.

The Handbook of Pharmaceutical Excipients teaches that colloidal silicon dioxide has many properties and is multipurpose. Colloidal silicon dioxide can be a suspending agent, glidant, antiadherent, flow conditioning agent, and a tablet disintegrant. The Handbook also teaches that microcrystalline cellulose also has multiple capacities such as being a diluent, disintegrant, suspending agent, and a pharmaceutical aid.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate a mixture of colloidal silicon dioxide and microcrystalline cellulose, as suggested by The Handbook, and produce the instant invention.

It would also be obvious for one of skill in the art at the time of the invention to improve the presentation of the composition such as the look and taste by incorporating include as flavorings are already taught by Olthoff, and colorings to the composition. Absent any evidence of criticality of the colorant being D&C Yellow Aluminum Lake, the adjustment of color as it would be based on market research and sampling, it is not inventive to discover the optimum presentation by routine experimentation.

One of ordinary skill in the art would have been motivated to do this because the colloidal silicon dioxide and microcrystalline cellulose are analogous materials when used as disintegrants or suspending agents and it would be well within the skill of one in

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the art to optimize the proportions to arrive at the desired disintegration time by adjusting the amounts. It is also, desirable for manufacturers to have analogous choices to substitute some or all of microcrystalline cellulose for the colloidal silicon dioxide when motivated by pricing, availability, or desired properties of the disintegrants used to produce the final product.

One of ordinary skill in the art would have been motivated to improve the presentation of the composition such as the look and taste since consumer opinion and compliance is dependent on not only if a product works, but also if they find the medication pleasant to consume, which is dictated by the look and taste of the product. The choice of color and flavors would be based on market research and sampling to maximize compliance and market share.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

All the critical elements are taught by the cited reference and thus the claims are rejected.



**Conclusion**

11. Claims 1-7, 19, 21-24, and 26 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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